Remarks

Claims 41-62 are pending in the subject application. Applicants acknowledge that claims 46-62 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 47, 48 and 52-62, amended claims 41-46 and added new claims 63-80. Support for the amendments and new claims can be found throughout the subject specification and in the claims as originally filed (see, for example, the originally presented claims, page 14, lines 26-34, and the paragraph bridging pages 1-2). Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 41-46, 49-51 and 63-80 are currently before the Examiner (with claims 46 and 49-51 standing withdrawn from consideration). Favorable consideration of the pending claims is respectfully requested.

Claim 41 is rejected under 35 U.S.C. § 112, second paragraph, as indefinite in the recitation of "or derivative thereof". Applicants respectfully assert that the claim as filed is definite. However, in the interest of advancing prosecution in this matter, the claim has been amended to indicate that the "derivative" is a humanized, chimeric or single chain antibody (support for this amendment can be found, for example, at page 14, lines 32-33 of the as-filed specification). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 41-45 rejected under 35 U.S.C. § 112, first paragraph, as nonenabled by the subject specification. The Office Action states the claims do not recite an antigen specificity for the 16D10 antibody. Applicants respectfully assert that the claims as filed are enabled; however, in an effort to advance prosecution in this matter, the claims have been amended to recite the antigen specificity of the 16D10 antibody. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 41-45 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action indicates that the specification lacks deposit information for the deposit of 16D10. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the

claimed invention. For example, the as-filed specification clearly indicates that the hybridoma producing the 16D10 monoclonal antibody was deposited with the Collection Nationale de Culture de Microorganismes (CNCM) in Paris, France on 16 March 2004 (see page 14, lines 18-21). Applicants further note that a deposit declaration executed by the undersigned accompanies this response and that the specification has been amended in accordance with the deposit requirements set forth in 37 C.F.R. §§1.801-1.809. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 41 and 43 are rejected under 35 U.S.C. § 102(b) as anticipated by Holmes *et al.* (2000). In addition, claims 41 and 43 are rejected under 35 USC §102(b) as anticipated by Takeda *et al.* (1992). The Office Action states that Holmes *et al.* teach a monoclonal 16D10 antibody of IgG type and therefore reads on the claimed 16D10 antibody, derivative thereof, or an antibody which essentially binds to the same epitope as monoclonal antibody 16D10. The Office Action indicates that Takeda *et al.* teach the monoclonal antibody J28 of IgG1 subclass which binds to human fetoacinar pancreatic protein (FAPP). Applicants respectfully assert that the Holmes *et al.* reference and the Takeda *et al.* reference do not anticipate the claimed invention.

Turning, first, to the rejection set forth over Holmes *et al.*, Applicants note that the antibody disclosed in Holmes *et al.* is reported to bind to recombinant human IL-18 whereas the claimed 16D10 monoclonal antibody binds to bile salt dependent lipase (BSDL) or fetoacinar pancreatic protein (FAPP). Accordingly, the claimed antibody is novel over the monoclonal antibody disclosed in Holmes *et al.* and reconsideration and withdrawal of the rejection is respectfully requested.

Turning, next, to the rejection set forth over Takeda *et al.* (1992), it is respectfully submitted that the cited reference fails to anticipate the claimed invention. As noted in the specification, the phrase "essentially binds to the same epitope or determinant as" an antibody of interest means that the antibody "competes" with said antibody of interest (see page 15 lines 34-35). Further, the as-filed specification indicates that and "the epitope recognized by antibody 16D10 is different from that recognized by antibody J28 because these two antibodies do not compete" (see page 19 lines 9-10). This difference in binding specificity is demonstrated in the ELISA and FACS competition studies reported in Experiment 4 at pages 42-43 of the as-filed specification. Consequently, the

disclosed J28 antibody of Takeda *et al.* does not anticipate claims 41 to 43 and reconsideration and withdrawal of the rejection is respectfully requested.

Claims 41-45 are rejected under 35 U.S.C. § 103(a) as obvious over Holmes *et al.* (2000) in view of Queen *et al.* (U.S. Patent No. 6,180,370) and Thirion *et al.* (1996). Claims 41-45 are rejected under 35 U.S.C. § 103(a) as obvious over Takeda *et al.* (1992) in view of Queen *et al.* (U.S. Patent No. 6,180,370) and Thirion *et al.* (1996). The Office Action notes that Queen *et al.* teach a method for preparing chimeric and humanized immunoglobulins for novel therapeutic agents and kits comprising said antibodies. Queen *et al.* is also cited as disclosing the potential advantages of humanized antibodies over mouse antibodies for use in human therapy. The Office Action states that Thirion *et al.* teach the advantages of single-chain antibody fragments for solid tumor cancer therapy and disclose single chain antibodies clear and more rapidly from the blood and penetrate faster and deeper into tissues than whole antibodies. The Office Action states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to produce a single-chain, humanized or chimeric version of the 16D10 antibody taught by Holmes *et al.* and of the J28 antibody taught by Takeda *et al.* and a kit comprising said antibodies. Applicants respectfully assert that the claimed invention is not obvious over the cited references and address both rejections in turn.

As the Patent Office is aware, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention (*CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) citing *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974)). In this regard, it is respectfully submitted that neither combination of references renders the claimed invention *prima facie* obvious. As noted above, Holmes *et al.* fail to teach a monoclonal antibody that binds to bile salt dependent lipase (BDSL) or human fetoacinar pancreatic protein (FAPP) and the antibody of Takeda *et al.* fails to recognize the same epitope as that specifically bound by the claimed 16D10 antibody. The teachings of Queen *et al.* (U.S. Patent No. 6,180,370) and Thirion *et al.* (1996) do not remedy this defect in the teachings of either Holmes *et al.* or Takeda *et al.* Thus, it is respectfully submitted that the combination of either Holmes *et al.* or Takeda *et al.* with the teachings of Queen *et al.* (U.S. Patent No. 6,180,370) and Thirion *et al.* (1996) fails to teach or suggest all the limitations of the claimed invention and a *prima facie* case of

obviousness has not been established and reconsideration and withdrawal of the rejections set forth under 35 U.S.C. § 103(a) is respectfully requested.

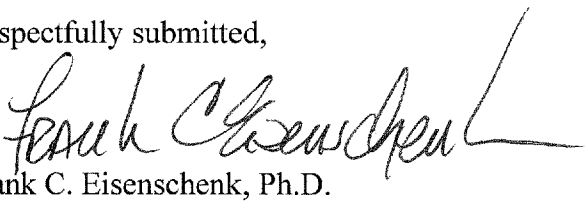
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



Frank C. Eisenschenk, Ph.D.
Patent Attorney
Registration No. 45,332
Phone No.: 352-375-8100
Fax No.: 352-372-5800
Address: P.O. Box 142950
Gainesville, FL 32614-2950

FCE/jb/sl
Attachment: Deposit Declaration